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REGION III
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SUBJECT: Derivation of Vinyl Chloride RBCs

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TO: RBC Table Users

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Because of the special considerations for vinyl chloride risk estimates identified in the *Toxicological Review of Vinyl Chloride in Support of Summary Information on the Integrated Risk Information System* (EPA/635R-00/004), this memo includes a demonstration of the assumptions behind the Region III RBCs for vinyl chloride. The method for calculating vinyl chloride risk shown in Section 5.3.5.1 of the Toxicological Review is not consistent with the typical RBC derivation shown in the "EPA Region III Risk-Based Concentration Table: Technical Background Information" memo, mainly because of the recommendation against pro-rating early-life exposure over the exposure duration.

In the following examples, the exposure assumptions are the same as identified in the "Technical Background Information" memo for all Region III RBCs. In these examples, however, the lifetime segments (6 years child, 24 years adult) are shown individually rather than through age-adjusted factors. For cancer risks, the sum of 6-year and 24-year exposures is equal to the age-adjusted 30-year exposure (and both are averaged over a 70-year lifetime).

Because non-cancer calculation methods are not affected by these issues, the RBC derivations shown here are for cancer only. As with all chemicals, these carcinogenic RBCs were then compared with the noncarcinogenic RBCs, and the lower of the two was displayed on the RBC table.

The general formula for cancer risk, pro-rated, is:

Oral:

$$\text{RBC} \times \text{Ingestion Rate} \times \text{Conversion Factor (if necessary)} \times \text{Exposure Frequency} \times \text{Exposure Duration} \times \text{Oral Cancer Slope Factor} / (\text{Body Weight} \times \text{\#Days/Yr} \times \text{Lifetime})$$

Inhalation:

$$\text{RBC} \times \text{Volatilization Factor (if necessary)} \times \text{Inhalation Rate} \times \text{Conversion Factor (if necessary)} \times \text{Exposure Frequency} \times \text{Exposure Duration} \times \text{Inhalation Cancer Slope Factor} / (\text{Body Weight} \times \text{\#Days/Yr} \times \text{Lifetime})$$

The non-pro-rated segments are the same, except "Exposure Duration" is removed from the numerator and "Lifetime" from the denominator of the equation. For the purposes of residential RBCs, "Exposure Frequency" is also removed from the numerator and "Lifetime" from the denominator, since the 350-day EF is practically a year-long exposure. It should be noted, however, that for exposures lasting only a few days, the non-prorated segment may very well merit prorating for days of exposure. In the case of RBCs, prorating by 350/365 would not greatly change the RBC, even if one considered this factor appropriate to include.

The CSFs for each segment are the lifetime CSF divided by 2, as shown in Section 5.3.5.1 of the Toxicological Review.

TAP WATER, "LIFETIME," CARCINOGENIC RBC

Pro-rated segment of childhood exposure + Non-prorated segment of childhood exposure + Adult exposure segment (pro-rated); repeated for each of ingestion and inhalation exposure

Ingestion

$$\begin{aligned} & [0.015 \text{ ug/l} \times 1 \text{ L/day} \times 1\text{E-}3 \text{ mg/ug} \times 350 \text{ days/yr} \times 6 \text{ yr} \times 0.72 \text{ per mg/kg/day} / (15 \text{ kg} \times 365 \\ & \text{days/yr} \times 70 \text{ yr})] \\ & + [0.015 \text{ ug/l} \times 1 \text{ L/day} \times 1\text{E-}3 \text{ mg/ug} \times 0.72 \text{ per mg/kg/day} / (15 \text{ kg})] \\ & + [0.015 \text{ ug/l} \times 2 \text{ L/day} \times 1\text{E-}3 \text{ mg/ug} \times 350 \text{ days/yr} \times 24 \text{ yr} \times 0.72 \text{ per mg/kg/day} / (70 \text{ kg} \times 365 \\ & \text{days/yr} \times 70 \text{ yr})] \\ & = 9\text{E-}7 \end{aligned}$$

Inhalation

$$\begin{aligned} & [0.015 \text{ ug/l} \times 0.5 \text{ L/m}^3 \times 12 \text{ m}^3/\text{day} \times 1\text{E-}3 \text{ mg/ug} \times 350 \text{ days/yr} \times 6 \text{ yr} \times 0.015 \text{ per mg/kg/day} / \\ & (15 \text{ kg} \times 365 \text{ days/yr} \times 70 \text{ yr})] \\ & + [0.015 \text{ ug/l} \times 0.5 \text{ L/m}^3 \times 12 \text{ m}^3/\text{day} \times 1\text{E-}3 \text{ mg/ug} \times 0.015 \text{ per mg/kg/day} / (15 \text{ kg})] \\ & + [0.015 \text{ ug/l} \times 0.5 \text{ L/m}^3 \times 20 \text{ m}^3/\text{day} \times 1\text{E-}3 \text{ mg/ug} \times 350 \text{ days/yr} \times 24 \text{ yr} \times 0.015 \text{ per mg/kg/day} / \\ & (70 \text{ kg} \times 365 \text{ days/yr} \times 70 \text{ yr})] \\ & = 1\text{E-}7 \end{aligned}$$

$$9\text{E-}7 + 1\text{E-}7 = 1\text{E-}6$$

$$\text{RBC} = 0.015 \text{ ug/l}$$

AIR, "LIFETIME," CARCINOGENIC RBC

Pro-rated segment of childhood exposure + Non-prorated segment of childhood exposure + Adult exposure segment (pro-rated)

$$\begin{aligned}
& [0.072 \text{ ug/m}^3 \times 12 \text{ m}^3/\text{day} \times 1\text{E-}3 \text{ mg/ug} \times 350 \text{ days/yr} \times 6 \text{ yr} \times 0.015 \text{ per mg/kg/day} / (15 \text{ kg} \times \\
& 365 \text{ days/yr} \times 70 \text{ yr})] \\
& + [0.072 \text{ ug/m}^3 \times 12 \text{ m}^3/\text{day} \times 1\text{E-}3 \text{ mg/ug} \times 0.015 \text{ per mg/kg/day} / (15 \text{ kg}) \\
& + [0.072 \text{ ug/m}^3 \times 20 \text{ m}^3/\text{day} \times 1\text{E-}3 \text{ mg/ug} \times 350 \text{ days/yr} \times 24 \text{ yr} \times 0.015 \text{ per mg/kg/day} / (70 \text{ kg} \times \\
& 365 \text{ days/yr} \times 70 \text{ yr})] \\
& = 1\text{E-}6
\end{aligned}$$

$$\text{RBC} = 0.072 \text{ ug/m}^3$$

{It should be noted that the recommended method for estimating inhalation cancer risks is to use the inhalation unit risk (IUR), in this case $4.4\text{E-}6 \text{ m}^3/\text{ug}$, instead of the inhalation CSF. For most RBCs, the difference between RBCs calculated using CSFs or IURs is relatively small. However, for vinyl chloride, because the non-prorated risk during early life is so significant, the difference between IUR-based and CSF-based calculations is greater. The air RBC derived using the IUR instead of the CSF would be:

$$\begin{aligned}
& [0.16 \text{ ug/m}^3 \times 350 \text{ days/yr} \times 6 \text{ yr} \times 4.4\text{E-}6 \text{ m}^3/\text{ug} / (365 \text{ days/yr} \times 70 \text{ yr})] \\
& + [0.16 \text{ ug/m}^3 \times 4.4\text{E-}6 \text{ m}^3/\text{ug}] \\
& + [0.16 \text{ ug/m}^3 \times 350 \text{ days/yr} \times 24 \text{ yr} \times 4.4\text{E-}6 \text{ m}^3/\text{ug} / (365 \text{ days/yr} \times 70 \text{ yr})] \\
& = 1\text{E-}6
\end{aligned}$$

$$\text{RBC} = 0.16 \text{ ug/m}^3$$

While EPA typically recommends the IUR approach, this approach eliminates any considerations of the effect of breathing rate and body weight on the cancer risk. This is appropriate for carcinogens that act directly on the respiratory system. However, vinyl chloride's cancer risk factors are based on liver cancer, a non-local effect. Therefore, the more conservative CSF method has been retained for this RBC table, to account for the possible effects of these exposure factors on the liver-cancer risk. It should be noted that there is an approximately twofold difference between the two methods for vinyl chloride.

Even though the tap water RBC incorporates an inhalation segment and therefore would seem to be affected by this issue also, the inhalation risk contributes a much smaller amount relative to ingestion, and the tap water RBC would therefore not change significantly if the inhalation portion were calculated via IUR instead of CSF.}

FISH AND INDUSTRIAL SOIL RBCs

Because these RBC scenarios involve adults only, the special pro-rating circumstances for early-life exposure do not apply. Therefore, these RBCs are derived in the traditional manner and are not shown in this memo.

RESIDENTIAL SOIL, "LIFETIME," CARCINOGENIC RBC

- Pro-rated segment of childhood exposure + Non-prorated segment of childhood exposure + Adult exposure segment (pro-rated)

$$\begin{aligned} & [0.09 \text{ mg/kg} \times 200 \text{ mg/day} \times 1\text{E-}6 \text{ kg/mg} \times 350 \text{ days/yr} \times 6 \text{ yr} \times 0.72 \text{ per mg/kg/day} / (15 \text{ kg} \times \\ & 365 \text{ days/yr} \times 70 \text{ yr})] \\ & + [0.09 \text{ mg/kg} \times 200 \text{ mg/day} \times 1\text{E-}6 \text{ kg/mg} \times 0.72 \text{ per mg/kg/day} / (15 \text{ kg})] \\ & + [0.09 \text{ mg/kg} \times 100 \text{ mg/day} \times 1\text{E-}6 \text{ kg/mg} \times 350 \text{ days/yr} \times 24 \text{ yr} \times 0.72 \text{ per mg/kg/day} / (70 \text{ kg} \times \\ & 365 \text{ days/yr} \times 70 \text{ yr})] \\ & = 1\text{E-}6 \end{aligned}$$

$$\text{RBC} = 0.09 \text{ mg/kg}$$